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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/512,914	02/25/00	BUCH J	PC 9919ARTR

HM12/0425

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EXAMINER
JIANG,S

ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 04/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/512,914	BUCH ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2001-02-05* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 84-172* is/are pending in the application.

4a) Of the above claim(s) *1-3, 84-98, 109-120, and 139-172* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *99-108, 121-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-3, and 84-172* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 and 7* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

This application claims priority to provisional application Serial No. 60/057275.

Election/Restrictions

Applicant's amendment and election with traverse of the invention of Group VII, Claims 99-117 and species election of the therapeutic treatment of the condition or disease of combined hypertension and hyerlipidemia in Group VII in Paper No. 6, submitted February 5, 2001 is acknowledged. The traversal is on the ground(s) that inventions I, VI and VII are all "closely related". This is found persuasive as to Groups I and VI, drawn to a composition product and a kit product comprising amlodipine/atorvastin in combination. Therefore, the Requirement for Restriction is modified as to Groups I and VI. The invention of Group I is herein combined with the invention of Group VI. However, the invention of Group VII is independent and distinct from Groups I and VI since Group VII is drawn to methods of therapeutic treatment herein. Inventions of Groups I and VI; and VII are independent and distinct each from other since they are related as product and process of use as discussed in the Requirement for Restriction and an undue burden on the Office is seen for the search all inventions herein, as discussed in the Requirement for Restriction. See the restriction Requirement page 4, the first and second paragraphs. Note that the search is not limited to patent files. Note that the search field for a composition or kit employing a combination of agents is different from the search field for a specified method of use employing the same combination of agents. The traversal is also on the ground(s) that

inventions I, VI and VII have traditionally been examined together and are issued routinely by the PTO in a single patent. This is not found persuasive since each application for patent is examined on its own merits, and patents are property and not available as precedent.

Therefore, claims 1-3 and 84-98 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 109-120, and 139-172 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 99-108 and 121-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messerli (U, PTO-892) and Nawrocki et al. (V, PTO-892) in view of Sever et al. (PTO-1449 submitted March 28, 2001).

Messerli discloses that the calcium antagonist, amlodipine, is useful in a method of the treatment of hypertensive and hyperlipidemia. See abstract and Table 4 of page 180S.

Nawrocki et al. discloses that the HMG-CoA reductase inhibitor, atorvastatin, is useful in a method of the treatment of hyperlipidemia. See title, abstract, and Table 1 of page 680.

The prior art does not expressly disclose a method for treating a mammal in need of therapeutic treatment or a method of treating combined hypertension and hyperlipidemia in a mammal comprising administering amlodipine and atorvastin. The prior art does also not expressly disclose that the particular amlodipine salt is amlodipine besylate and the particular atorvastatin salt is hemicalcium salt of atorvastatin. The prior art does not expressly further disclose that these two active ingredients may be administered simultaneously or sequentially in either order.

Sever et al. teaches that combining antihypertensive therapy with lipid-lowing drugs would be beneficial in the therapeutic treatment therein. See page S32, 2nd paragraph of left column and page S33, the last paragraph of left column.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine amlodipine and atorvastin to be administered in a method for treating a mammal in need of therapeutic treatment or a method of treating combined hypertension and hyperlipidemia in a mammal, and to employ the particular amlodipine salt, amlodipine besylate, and the particular atorvastatin salt, hemicalcium

salt of atorvastatin in the claimed methods, and to administer two active ingredients herein simultaneously or sequentially in either order.

One having ordinary skill in the art would have been motivated to combine amlodipine and atorvastin to be administered in a method for treating a mammal in need of therapeutic treatment or a method of treating combined hypertension and hyperlipidemia in a mammal since the calcium antagonist, amlodipine, is known to be useful in a method of the treatment of hypertension and hyperlipidemia, whereas the HMG-CoA reductase inhibitor, atorvastatin, is known to be useful in a method of the treatment of hyperlipidemia according to Messerli and Nawrocki et al. Therefore, one of ordinary skill in the art would have found it obvious to combine the known active agents useful in the same method into a single composition for the same purpose. Moreover, the combination antihypertensive therapy with lipid-lowing drugs taught by Sever further provides motivation for the claimed method. Additionally, one of ordinary skill in the art would have been motivated to employ the particular amlodipine salt, amlodipine besylate, and the particular atorvastatin salt, hemicalcium salt of atorvastatin in the claimed methods, and to administer two active ingredients herein simultaneously or sequentially in either order because the determination of a known pharmaceutically acceptable salt to be administered, routes of administration, and dosage regimen is considered well within the skill of artisan.

Since all method and composition components herein are known to be useful to treat hypertension and hyperlipidemia, it is considered prima facie obvious to combine them into a single method and composition useful for the very same purpose. At least

additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 99-108 and 121-138 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 90-97 and 107-118 of copending Application No. 09/513,889. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to methods for the therapeutic treatments such as hypertension and hyperlipidemia which may comprise amlodipine and rivastatin. The claim of the instant application is drawn to the method for the same treatments comprising amlodipine and atorvastatin. One having ordinary skilled in the art would have been motivated to employ rivastatin or atorvastatin in combination with amlodipine

in the same claimed methods since statins such as rivastatin and atorvastatin are well known HMG-CoA reductase inhibitors, which are useful for the very same purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 18, 2001

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